NATIONAL ASSOCIATION
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March 5, 2003

Office of Information & Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th Street, N.W., Room 10235
Washington, D.C. 20503

ATTN: Stuart Shapiro
Desk Officer for FDA

RE: Docket No. 02N-0278

Dear Sir:

These Comments are submitted on behalf of the Members of the National Association of Beverage Importers, Inc., (NABI). NABI is a national trade association that represents the interests of importers of beer, wine, and distilled spirits. NABI Members are responsible for the importation of a major share of all alcohol beverages that are imported into the United States.

NABI Members welcome this opportunity to provide comments to the Office of Management and Budget (OMB). The Paperwork Reduction Act of 1995 subjects these proposed rules to review by OMB. We ask that OMB review these regulations as they relate to the collection of information and to the burden placed on large and small businesses alike. We believe that FDA is proposing regulations that are unnecessary for the proper performance of FDA's functions and that they duplicate the collection of information already gathered by the U.S. Customs Service. FDA has failed to consider options that would minimize the burden of collection on respondents.

In August, 2002, NABI was part of an alcohol beverage coalition comprised of nine industry representatives that was formed to respond to FDA's request for comments by stakeholders as FDA developed proposed regulations implementing the provisions of the "Bioterrorism Act of 2002," (hereafter referred to as "the Act"). The coalition submitted comments to FDA on August 30, 2002 (See attached Exhibit No. 2).

02N-0278 C 45

ROBERT J. MAXWELL
PRESIDENT

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BERNADEEN P. EMAMALI
CORPORATE SECRETARY

In that August 30, 2002, comment, the coalition argued that FDA should not propose regulations that would duplicate regulations already in place and administered by other agencies. We believed then, and continue to believe now, that the U.S. Customs Service collects all of the information that would be necessary for FDA to carry out its responsibilities under the Bioterrorism Act.

At this time, we urge OMB to insist that FDA not adopt regulations that would be duplicative of regulations already in place and administered by other Federal agencies. In that regard, Sections 302 (c) and 314 of the Act clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act, and to facilitate its implementation through a clear allocation of Federal agency activities. The Congressional Record is further evidence of such intent. The Senate proposal authorized the "Secretary" to require the maintenance and retention of other records relating to food safety in consultation with other Federal departments and agencies that regulate food safety. (148 Cong Rec H 2685.) Since the Secretary had authority under Section 702(a) of the FFDCA to issue regulations for the efficient enforcement of the Act in combination with other provisions, the Senate proposal was not adopted. (148 Cong Rec H 2685.)

The House of Representatives has also advocated close coordination with other Federal agencies, such as U.S. Customs Service, in implementing the notice requirement with a goal of minimizing and eliminating unnecessary, multiple, and redundant notifications (147 Cong Rec E 2388) and encouraging simplicity and cooperation with respect to the registration requirement, reducing paperwork and the reporting burden on facilities (147 Cong Rec E 2388.) Therefore, Congress recognized that the Act called upon functions of other Federal agency activities and intended to coordinate, rather than duplicate, such functions.

Understanding the need to immediately obtain information relating to foods imported or offered for import into the United States in reaction to a crisis, NABI urges the FDA to implement a coordinated strategy with other Federal agencies that have established regulatory measures governing beverage alcohol. This clear allocation of Federal agency activities, such as TTB and Customs vis-à-vis their respective regulatory schemes governing beverage alcohol, will best utilize the procedures and processes already in place to most efficiently "develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply" – the stated purpose of Title III of the Act.

We will now address the specific questions asked relating to the Paperwork Reduction Act of 1995 that were contained in this rulemaking.

1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility

The collection of the information in question in a "stand alone" FDA system is duplicative. The proposed regulations appear to have been written without taking into consideration the "24 hour" rule implemented by the U.S. Customs Service on February 3, 2003. Under this new rule an ocean carrier must supply the U.S. Customs Service with detailed manifest information twenty-four (24) hours in advance of the cargo being loaded on the ship in the port of embarkation. The manifest information, the entry paperwork, and the OASIS system, all on file with the U.S. Customs Service, clearly satisfy the prior notification requirements of the Act.

We have prepared a comparison of the information required by these proposed regulations and the information currently submitted to U.S. Customs when an importer makes an entry. (See attached Exhibit No. 1) As you can see, all of the information that FDA needs for its purposes is already available in the U.S. Customs entry documentation or is readily available in other commercial records, if needed.

Even if FDA can gather the information from either the U.S. Customs Service or from its own stand alone system, FDA has not made it clear as to how it will use the information. The number of "prior notices" will be so voluminous that it is doubtful that FDA will be able to do anything meaningful with it that U.S. Customs isn't already doing. Accordingly, we do not feel that this requirement to file duplicative information with the FDA will have practical utility or benefit that would outweigh the additional burden on businesses.

2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used

We believe that the FDA estimate of burden hours caused as a result of the proposed regulations is fatally flawed. A quick check of a sample of NABI Members revealed that Members would average 1200 responses per month, not the 23 per month estimated by FDA. The total annual responses for the average

NABI Member would be 14,400 responses. Converting 14, 400 responses into staff years, using the FDA assumption of 1 hour per response, equals approximately 7 staff years that each company would have to expend to comply with the proposed regulations. That expenditure of money by a company seems to be an unreasonable burden for a company to bear – just to re-submit information that is already on file with the U.S. Customs Service. You should also bear in mind that the average cost to employ a person to do this work in the cities where the importers are located is $50,000.00 per year.

We think that the number of respondents assumed by FDA is far too low. Using FDA assumptions, alcohol beverage importers would be approximately 5% of all food importers in the United States. Considering the nature and volume of other food imports, that assumption is highly unlikely.

It is obvious that this is a major rule with significant impact on small business. Using our assumptions, the aggregate cost to the private sector could easily exceed the $112 million dollar threshold specified in Title II of the Unfunded Mandate Reform Act of 1995. It would appear that a cost benefit analysis must be conducted before FDA finalizes these regulations. The proposed rule is a significant rule as defined by that Act.

3) Ways to enhance the quality, utility, and clarity of the information to be collected

We suggest that the amount and kind of information requested by FDA in the "prior notice" is significantly more than that required by Section 307 of Title III of the Bioterrorism Act. The quality, utility, and clarity of the information would be enhanced if FDA would limit its request for information to only those items specified in the law.

It is important to note here that Section 307 of Title III of the Bioterrorism Act directs the Secretary (HHS) to consult with the Secretary of the Treasury before issuing "prior notice" regulations. It would appear that the Congress was trying to avoid duplication by including this language.

4) Ways to minimize the burden of the collection of information on respondents

The best way to minimize the burden would be for FDA to accept those filings already made with the U.S. Customs Service as the "prior notice" mandated by the Bioterrorism Act.

In the Final Rule, FDA should limit the information requested to that mandated by law.

Conclusion

In summary, NABI Members recommend that FDA work with other agencies that have jurisdiction governing the importation of alcohol beverages in order to coordinate regulatory requirements on the private sector. The U.S. Customs Service and the Tax and Trade Bureau of Treasury both have regulatory authority over the importation of an alcohol beverage. We believe that the regulations proposed by FDA unnecessarily duplicate regulations issued by those agencies. FDA should re-evaluate the need for its "prior notice" regulation in light of the 24 hour advance notice now required by the U.S. Customs Service.

FDA should also conduct the costs benefit analysis as required by Title II of the Unfunded Mandate Reform Act of 1995 before it moves to finalize these "prior notice" regulations.

We thank you for this opportunity to comment on these proposed regulations. We ask that OMB use the powers vested in it by law to ensure that FDA regulations do not unnecessarily burden the private sector or negatively affect the economy. We stand ready to work with you at any time and to assist FDA in the drafting of regulations that meet the requirements of the law without placing an unnecessary burden on the regulated industry.

If we can be of further assistance, please do not hesitate to call on us.

Sincerely,

Robert J. Maxwell
President – NABI

Attachments (2)
August 30, 2002 Joint Industry Comment
Exhibit No. 1 - Comparison Chart

BIO-TERRORISM REQUIREMENTS

- The proposed rule would require the prior notice to contain the following information for each imported food entry:

FORM		
7501	(A)	– Identification of the submitter, including name and firm information.
7501	(B)	– Entry type and U.S. Customs System (ACS) entry number, or other U.S. Customs identification number for the import.
3461	(C)	– The location of any imported food products held at the port of entry for failure to submit an adequate prior notice.
FDA ENTRY + 7501	(D)	– The identification of the articles of food, including complete FDA product code, the common or usual name or market name, the trade or brand name (if different from the common or market name), the quantity described from the smallest package size to the largest container, and the lot or code numbers or other identifier (if applicable).
7501, 3461	(E)	– The identification of the manufacturer.
N/A	(F)	– The identification of the grower, if known.
7501	(G)	– The originating country.
OCEAN B/L	(H)	– The identification of the shipper.
7501	(I)	– The country from which the article of food was shipped.
7501	(J)	– The anticipated arrival information: location, date, and time.
RMS 7501 - 3461	(K)	– U.S. Customs entry process information.
7501	(L)	– The identification of the importer, owner, and consignee.
7501	(M)	– The identification of the carrier.

EXHIBIT No.1

(A) (B)

4. Entry Date	5A. Port Code	
6. Bond No.	7. Bond Type Code	8. Broker/Importer File No.
9. Licensed Container Name and Address	10. Consignee No.	11. Importer of Record Name and Address (L) / 12. Importer No.
		13. Exporting Country (I) / 14. Export Date
		15. Country of Origin (G) / 16. Missing Documents
		17. I.T. No. / 18. I.T. Date
19. B/L or AWB No.	20. Mode of Transportation	21. Manufacturer I.D. (E) / 22. Reference No.
23. Importing Carrier (M)	24. Foreign Port of Lading	25. Location of Goods/G.O. No.
26. U.S. Port of Unlading	27. Import Date (J)	

28. Line No.	29. Description of Merchandise: 29A. A. T.S.U.S.A. No. / B. ADA/CVD Case No.	29B. A. Gross Weight / B. Net Quantity	29C. Net Quantity in T.S.U.S.A. Units	31. A. Entered Value / B. CHGS / C. Relationship	34. A. T.S.U.S.A. Rate / B. ADA/CVD Rate / C. I.R.C. Rate / D. Visa No.	35. Duty and I.R. Tax: Dollars	Cents
	(D) (E) (G)						

39. Declaration of Importer of Record (Owner or Purchaser) or Authorized Agent	U.S. CUSTOMS USE	TOTALS
I declare that I am the importer of record and that the actual owner, purchaser, or consignee for whom purchase is made is as shown above. OR ☐ owner or purchaser of Agent thereof.	A. Liq. Code	B. Ascertained Duty / 37. Duty
I further declare that the merchandise ☐ was obtained pursuant to a purchase or agreement to purchase and that the prices set forth in the invoice are true. OR ☐ was not obtained pursuant to a purchase or agreement to purchase and the statements in the invoice as to value or price are true to the best of my knowledge and belief.		C. Ascertained Tax / 38. Tax
I also declare that the statements in the documents hereto that fully disclose to the best of my knowledge and belief the true price, value, quantities, discounts, drawbacks, bounties, commissions, and royalties, and that all goods or services provided to the seller of the merchandise either free or at reduced cost are fully disclosed. I will immediately furnish to the appropriate customs officer any information showing a different state of facts.		D. Ascertained Other / 39. Other
		E. Ascertained Total / 40. Total

Notice required by Paperwork Reduction Act of 1980. This information is required to ensure that importers/consignees are complying with U.S. Customs laws, to allow us to compute and collect the right amount of money to enforce other agency requirements, and to collect accurate statistical information on imports. Your response is mandatory.

41. Signature of Declarant, Title, and Date

CASHIER

Customs Form 7501 (11

EXHIBIT No.1

EXHIBIT No.1

Print Key Output

5769SS1 V4R5M0 000526 BARTHPHL 02/27/03 Page 1 15:26:36

Display Device . . . . . : RQ
User . . . . . : CHARLENE

FDA Screen 1 27-39788-0 113 2315385-5 001 001 01 CONSUMPTION ENTRY

Commercial Description: Red Wine .. BTL size per case etc.

Product Code FDA CODE
Ctry of Prod. CL Country of Origin

*Actual Manuf. CLPATCH1265AH — *Actual Shipper CLPATCH1265AH
FEI Number FDA Value 4

Brand Name Advertname

Affirm/Compliance: Code Qualifier

Quantity#1 ____ Unit ____ Accumulated FDA Value
Quantity#2 ____ Unit ____ Line Item Value 316575.00

Cargo Storage Status *Container Dimensions ___ X ___ X ___
*Contact Name: Phone #:

HELP Available F02
Cm1 Quit Cm3 Delete Cm5 Replay Cm7 Exit Cm10 Accept
Cm12 Disclaimer Cm15 Dup Previous Cm21 Additional Info

→ Units are in FDA Codes.
Must Supply From Lg → Small.
ex. cont → ctns → L →.
→ optional. but suppose to.

(1)

August 30, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: (1) Section 303 – Docket No. 02N-0275 (Detention)
(2) Section 305 – Docket No. 02N-0276 (Registration)
(3) Section 306 – Docket No. 02N-0277 (Recordkeeping)
(4) Section 307 – Docket No. 02N-0278 (Prior Notice)

Dear Sir/Madam:

The undersigned are a coalition of trade associations (see Attachment A) representing all tiers of the beverage alcohol industry. Members of our associations are involved in the production, importation, distribution/wholesaling, and retailing of beverage alcohol products that are sold throughout the United States.

On behalf of our respective members, we welcome the opportunity to provide initial comments concerning the Food and Drug Administration's (FDA) proactive efforts to liaise with the foods community in implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Act). We fully support this FDA initiative, which is designed to create a focused regulatory scheme that does not unnecessarily duplicate existing statutory and/or regulatory requirements currently in place. To that end, our comments focus upon how the directives of the above-referenced Sections of the Act already are met and satisfied by the existing extensive regulatory scheme governing beverage alcohol.

Since the 1930s, the Bureau of Alcohol, Tobacco and Firearms (BATF) and its predecessor agencies have regulated the beverage alcohol industry in terms of both import and domestic trade.[1] BATF has a comprehensive set of regulations that governs the production, manufacture, importation, and distribution of beverage alcohol products. All persons engaged in the business of producing, importing and distributing beverage alcohol products in the United States must obtain a permit from BATF or be registered with BATF. The beverage alcohol industry also is governed by an extensive regulatory scheme administered by BATF, which, among other things, requires industry members to strictly account for all products. Simply put, the existing regulations enforced by BATF more than satisfy the provisions of this Act.

[1] See generally, Federal Alcohol Administration Act, 27 U.S.C. §§ 121-211, Internal Revenue Code 26 U.S.C. §§ 5001-5691, and Title 27, Code of Federal Regulations

In addition, industry members involved in the production, importation and distribution of beverage alcohol products are licensed by each State in which they do business. Each State also has regulations that require recordkeeping and mandate the filing of periodic reports of beverage alcohol products shipped into and/or sold in that State. Although excluded from the scope of the Act, beverage alcohol retailers also are licensed by the States in which they do business.

The U.S. Customs Service further regulates importers of beverage alcohol products. Importers must maintain records to establish upon request that goods imported have been classified correctly, taxes have been paid, and the importer of record has complied with all regulations specifically dealing with beverage alcohol. Further, as discussed more fully below, Customs has several initiatives in place, such as the Container Security Initiative, that requires extensive information about U.S. bound shipments at least 24 hours before the vessel sails to the United States.

We urge FDA to avoid proposing or adopting regulations that would be duplicative of regulations already in place and administered by other federal agencies. In that regard, Sections 302(c) and 314 clearly contemplate and direct the efficient use of government resources to effectuate the goals of this Act and to facilitate its implementation by a clear allocation of federal agency activities. This clear allocation of responsible action among federal agencies, such as BATF and the Customs Service vis-à-vis their respective regulatory schemes governing beverage alcohol, will best utilize the procedures and processes already in place to most efficiently "develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply," the stated purpose of Title III of the Act.

Duplicative regulations and unnecessary regulations are costly and create inefficiencies, as well as spawn potential confusion within the regulated community. Further, such measures impose unnecessary burdens upon regulators and the regulated community and thereby divert valuable time and resources away from government and industry efforts to protect the food supply from bioterrorist threats -- an objective that all of us fully support.

Finally, we urge that the resources and appropriations allocated to implement the Act be available to the federal agencies, such as BATF, that are a critical component in effectuating its provisions. In addition, such agencies also should have available the necessary resources and funds to meet various procedural elements of the Act, such as the electronic filing directive set forth in Section 305(d).

The following are our comments regarding specific Sections of the Act.

Section 303 – Administrative Detention

No person can hold a federal permit to produce, import or distribute beverage alcohol if that person has been convicted of a felony within five years prior to the date of application or within three years of the date of application to have been convicted of a misdemeanor relating to beverage alcohol. Without a permit, importers, distillers, vintners, and distributors cannot

engage in the beverage alcohol business. Permits can be revoked or suspended for reasons specified in federal law. The current permit system for beverage alcohol producers, importers and wholesalers/distributors is far more restrictive and gives the government greater control than anything contemplated in instant Act.

Section 305 – Registration of Food Facilities

Requiring a producer, importer, or distributor of beverage alcohol to register with FDA would be a duplication of existing licensing and/or permit requirements. All importers, domestic producers and wholesalers/distributors of beverage alcohol must obtain a permit from the federal government. While brewers are not required to obtain a permit, they must register with BATF. Any applicant for a permit or registration with BATF must go through extensive background and financial investigations. Foreign producers can only import beverage alcohol through an entity that holds a Federal Basic Importer's Permit.

Section 306 – Maintenance and Inspection of Records for Foods

Under current federal laws and regulations, importers, producers and distributors/ wholesalers of beverage alcohol must maintain "one up and one down" records. During normal business hours, these records must be kept and made available for review by a federal officer. The objectives of Section 306 are met or exceeded by current BATF recordkeeping requirements/regulations. Any additional recordkeeping requirement by FDA would be duplicative and unnecessary.

Section 307 – Prior Notice of Imported Food Shipment

The U.S. Customs Service already receives advance notice of the arrival of a ship and of the ship's manifest well in advance of the ship's arrival. Given the Customs Service's various security initiatives, there is no need for FDA to issue more regulations that would require something already required by the U.S. Customs Service. For example, Customs is in the process of finalizing its new requirements that would require ocean carriers and non-vessel-operating common carriers to present detailed cargo manifests 24 hours before a container is loaded onto a ship. Shippers – food importers – play a crucial role in satisfying these requirements.

The Custom's checklist requires fifteen (15) information elements that are far more detailed than the directives of the Act. These information elements are: (1) foreign port of departure; (2) carrier SCAC code; (3) voyage number; (4) date of scheduled arrival in first U.S. port; (5) numbers and quantities from carrier's master or house bill of lading; (6) first port of loading, or first port of receipt, of the cargo by the inbound carrier; (7) a precise description (or the Harmonized Tariff Schedule numbers if the HTS classification is provided by the shipper) and weight of the cargo, or, if the container is sealed, the shipper's declared description and weight of the cargo (generic descriptions, specifically freight-all-kinds, general cargo, and STC (said to contain) are not acceptable); (8) shipper's name and address, or an identification number, from all bills of lading; (9) consignee's name and address, or the owner's or owners' representative's name and address, or an identification number, from all bills of lading; (10) advise Customs when actual boarded quantities do not equal quantities indicated on the relevant bills of lading (carriers

are not required to verify quantities in sealed containers); (11) vessel name, national flag and vessel number; (12) foreign country of origin where cargo is loaded onto vessel; (13) hazardous-material indicator; (14) container number (for containerized shipments); and (15) seal number affixed to container.

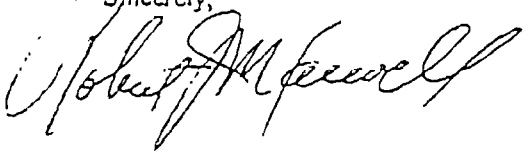
Customs' efforts to improve security impose requirements beyond the dictates set forth in the Act. U.S. companies must educate their suppliers not only about the new manifest rules referenced above, but also about the Customs-Trade Partnership Against Terrorism (C-TPAT) and other security measures. Although technically a voluntary program, C-TPAT is becoming an industry standard.

Conclusion

In summary, we recommend that FDA meet with other agencies that have regulations and jurisdictions to govern the importation, production and distribution of beverage alcohol in order to coordinate responsibilities. Such a liaison will avoid duplication of government resources, government manpower and government regulation. We submit that this suggested course of action will enable the federal government and the food industry to focus their resources more efficiently and effectively upon efforts that will enhance security and will avoid unnecessary and redundant burdens that otherwise could be imposed upon both enforcement and compliance efforts.

Thank you for the opportunity to present our views concerning FDA's actions to implement the Bioterrorism Act. We stand ready to work with you at any time to assist FDA in the development of implementing regulations that will result in the efficient and effective implementation of this Act. If we can be of any further assistance, please do not hesitate to call on us.

Sincerely,



Attachment A

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3/5/03

TO: Stuart Shapiro (202) 395 6974

FROM: Bob Maxwell
NABI

RE: FDA Docket No. 02N-0276

We tried to hand deliver the attached to you but we could not get past yal security. I will put the originals in the mail to you

Robert J. Maxwell

Number of pages (including cover page)

If you do not receive a clear copy, or do not receive the entire document please call us at (240)453-9998